Version with Markings to Show Changes Made

In the Specification:

Please amend the specification as follows:

On page 12, the last full paragraph:

When using jojoba oil as the source of the wax esters, the composition of the naturally occurring fatty substituent in jojoba oil are 1%, 44%, 45%, and 9% for C_{18}, C_{20}, C_{22}, and C_{24}, respectively. The alcoholysis reaction described above would provide the long chain monounsaturated alcohols in equivalent proportions. Thus, the most preferred embodiment of the composition according to the present invention comprises long chain monounsaturated fatty alcohols wherein wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

In the Claims:

Please amend the claims as follows:

1. (Canceled)

2. (Currently Amended) A method of treating virus-induced and inflammatory diseases of skin and membranes in humans or animals, comprising topical application of a composition comprising of one or more of the monounsaturated alcohols octadecenol, eicosenol, docosenol, and tetracosenol in a concentration of from 0.1 to 25 percent by weight in a physiologically compatible carrier to the inflamed skin or membrane of the patient to be treated, the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12 and M^+ is a monovalent alkali metal ion.

3. (Currently Amended) The method according to claim 2 wherein the composition further comprises one or more of the mixed esters according to the formula R^1-COO-R^2, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12, and R^2 is an alkyl group or other aliphatic group~~, preferably~~ comprised of 1 to 12 carbon atoms.

4. (Canceled)

5. (Currently Amended) The method of claim 2 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

6. (Currently Amended) The method of claim 3 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

7. (Canceled)

8. (Currently Amended) A method treating virus-induced and inflammatory diseases of skin and membranes in humans or animals, comprising topical application of a composition comprising of one or more of the monounsaturated alcohols docosenol, tetracosenol and hexacosenol ~~in a concentration of from 0.1 to 25 percent by weight~~ in a concentration of from 0.1 to 25 percent by weight, all in a physiologically compatible carrier to the inflamed skin or membrane of the patient to be treated, the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12 and M^+ is a monovalent alkali metal ion.

9. (Currently Amended) The method of claim 8 wherein the composition further comprises mixed esters according to the formula R^1-COO-R^2, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12, and R^2 is an alkyl group or other aliphatic group~~, preferably~~ comprised of 1 to 12 carbon atoms.

10. (Canceled)

11. (Currently Amended) The method of claim 8 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

12. (Currently Amended) The method of claim 9 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

13. (Canceled)

14. A method of treating humans or other mammals for viral infections, comprising intravenous introduction into the human or other mammal to be treated ~~suspected of having a viral infection~~ with an effective amount of from about 0.1 mg to about 2 gm per 50 kg of body weight of a composition consisting of one or more C_{18} to C_{24} monounsaturated alcohols in a physiologically compatible carrier, the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12 and M^+ is a monovalent alkali metal ion.

15. (Currently Amended) The method of claim 14 wherein the composition further comprises mixed esters according to the formula R^1-COO-R^2, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12, and R^2 is an alkyl group or other aliphatic group~~, preferably~~ comprised of 1 to 12 carbon atoms.

16. (Canceled)

17. (Currently Amended) The method of claim 14 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

18. (Currently Amended) The method of claim 15 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

19. (Canceled)

20. (Currently Amended) A method of treating humans or other mammals for viral infections, comprising intramuscular introduction into the human or other mammal to be treated ~~suspected of having a viral infection~~ with an effective amount of from about 0.1 mg to about 2 gm per 50 kg of body weight of a composition consisting of one or more C_{18} to C_{24} monounsaturated alcohols in a physiologically compatible carrier, the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12 and M^+ is a monovalent alkali metal ion.

21. (Currently Amended) The method of claim 20 wherein the composition further comprises mixed esters according to the formula R^1-COO-R^2, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10

and 12, and R^2 is an alkyl group or other aliphatic group~~, preferably~~ comprised of 1 to 12 carbon atoms.

22. (Canceled)

23. (Currently Amended) The method of claim 20 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

24. (Currently Amended) The method of claim 21 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

25. (Canceled)

26. (Currently Amended) A method of treating humans or other mammals for viral infections, comprising trans-mucus membranal introduction into the human or other mammal to be treated ~~suspected of having a viral infection~~ with an effective amount of from about 0.1 mg to about 2 gm per 50 kg of body weight of a composition consisting of one or more C_{18} to C_{24} monounsaturated alcohols in a physiologically compatible carrier, the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12 and M^+ is a monovalent alkali metal ion.

27. (Currently Amended) The method of claim 26 wherein the composition further comprises mixed esters according to the formula R^1-COO-R^2, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12, and R^2 is an alkyl group or other aliphatic group~~, preferably~~ comprised of 1 to 12 carbon atoms.

28. (Canceled)

29. (Currently Amended) The method of claim 26 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

30. (Currently Amended) The method of claim 27 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

31. (Canceled)

32. (Currently Amended) A method of treating humans or other mammals for viral infections, comprising transdermal penetration into the human or other mammal to be treated ~~suspected of having a viral infection~~ with an effective amount of from about 0.1 mg to about 2 gm per 50 kg of body weight of a composition consisting of one or more C_{18} to C_{24} monounsaturated alcohols in a physiologically compatible carrier, the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+, wherein R^1 comprises CH_3-$(CH_2)_7$-

$CH=CH-CH_2-(CH_2)_x-$,and x is 6, 8, 10 and 12 and M^+ is a monovalent alkali metal ion.

33. (Currently Amended) The method of claim 32 wherein the composition further comprises mixed esters according to the formula R^1-COO-R^2, wherein R^1 comprises $CH_3-(CH_2)_7-CH=CH-CH_2-(CH_2)_x-$,and x is 6, 8, 10 and 12, and R^2 is an alkyl group or other aliphatic group~~, preferably~~ comprised of 1 to 12 carbon atoms.

34. (Canceled)

35. (Currently Amended) The method of claim 32 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

36. (Currently Amended) The method of claim 33 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

37. (Canceled)

38. (Withdrawn)

39. (Withdrawn)

40. (Canceled)

41. (Withdrawn)

42. (Withdrawn)

43. (Canceled)

44. (Withdrawn)

45. (Withdrawn)

46. (Canceled)

47. (Withdrawn)

48. (Withdrawn)

49. (Canceled)

50. (Withdrawn)

51. (Withdrawn)

52. (Canceled)

53. (Withdrawn)

54. (Withdrawn)

55. (Canceled)

56. (Withdrawn)

57. (Withdrawn)

58. (Canceled)

59. (Withdrawn)

60. (Withdrawn)

61. (Canceled)

62. (Withdrawn)

63. (Withdrawn)

64. (Canceled)

65. (Withdrawn)

66. (Withdrawn)

67. (Canceled)

68. (Withdrawn)

69. (Withdrawn)

70. (Canceled)

71. (Withdrawn)

72. (Withdrawn)

73. (Canceled)

74. (Withdrawn)

75. (Withdrawn)

76. (Canceled)

77. (Withdrawn)

78. (Withdrawn)

79. (Canceled)

80. (Withdrawn)

81. (Withdrawn)

82. (Canceled)

83. (Withdrawn)

84. (Withdrawn).

85. (Canceled)

86. (Currently Amended) A method of treating humans and mammals for viral infections comprising introducing a composition consisting essentially of one or more monounsaturated alcohols having from 18 to 24 carbons through a membrane into the circulatory system of a human or mammal to

be treated ~~suspected of having a viral infection~~ with an effective amount of from about 0.1 mg to about 2 gm per 50 kg of body weight comprising inserting such alcohol composition in a physiologically acceptable liquid, cream, gel or suppository carrier into the anus or vagina of the human or mammal to be treated, the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12 and M^+ is a monovalent alkali metal ion.

87. (Currently Amended) The method of claim 86 wherein the composition further comprises mixed esters according to the formula R^1-COO-R^2, wherein R^1 comprises CH_3-$(CH_2)_7$-CH=CH-CH_2-$(CH_2)_x$-,and x is 6, 8, 10 and 12, and R^2 is an alkyl group or other aliphatic group~~, preferably~~ comprised of 1 to 12 carbon atoms.

88. (Canceled)

89. (Currently Amended) The method of claim 86 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

90. (Currently Amended) The method of claim 87 wherein said alcohols are comprised of relative proportions of octadecenol of ~~is~~ about 1%, eicosenol of ~~is~~ about 44%, docosenol of ~~is~~ about 45%, and tetracosenol of ~~is~~ about 9%.

REMARKS

Claim Status

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87 and 89-90 are pending and have been amended above.

Claim Objection

The examiner has objected to claims 14-15, 17-18, 20-21, and 23-24 as being duplicated of one another.

The applicant, in examining claims 14-15, 17-18, 20-21 and 23-24 believes them to not be duplicative. Claims 14-15 and 17-18 are grouped together, where claim 14 is the independent claim and claims 15 and 17-18 depend either upon claims 14 or 15. Claims 20-21 and 23-24 are grouped together, where claim 20 is the independent claim and claims 21 and 23-24 depend either upon claims 20 or 21. Claims 14 and 20, while being mostly identical, differ in that claim 14 requires **intravenous** introduction as a step in the claimed method and claim 20 requires **intramuscular** introduction as a step in the clamed method. Therefore, the two sets of claims are clearly not duplicative. For this reason, the applicant respectfully requests that the examiner withdraw the instant objection.

The examiner has objected to claims 2-3, 5-6, 8-9, and 11-12 for minor informalities. The examiner points to a missing word "of" as being missing in the phrase "A method treating" (in claim 2, upon which claims 2, 5-6, 8-9 and 11-12 depend).

While the applicant believes that the current wording "a method treating" is correct English, in order to advance this application to issuance has amended claim 2 above to include the word "of" between "method" and "treating" in accordance with the examiners request. Therefore the applicant respectfully requests that the examiner withdraw the instant objection.

Claim Rejections - 35 U.S.C. § 112

The examiner has rejected claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87 and 89-90 as being indefinite for failing to particularly point out and distinctly claim the subject mater that the applicant regards as the invention.

Specifically, the examiner believes that the term "relative", in claims 5-6, 11-12, 17-18, 23-24, 29-30, 35-36 and 89-90 is a relative term that renders these claims indefinite since the term "relative" is not defined in the specification.

The applicant respectfully disagrees with the examiner. While the word "relative" is indeed used within the specification, it is consistently used according to the ordinary dictionary meaning of the word (One of the Merriam-Webster definitions of the word "relative" is "expressed as the ratio of the specified quantity (as an error in measuring) to the total magnitude (as the value of a measured quantity) or to the mean of all the quantities involved"). Thus, use of the word "relative", which is a term that is found in the claims in uncountable numbers of US patents, does not render the instant claims indefinite. However, the applicant has noticed that these claims include a typographical error in that the word "is" found after each component should really be "of". This typographical error may confuse some readers, thus the applicant has amended the claims appropriately above.

The examiner points out that the phrase "from 0.1 to 25 percent by weight" is repeated twice in claim 8.

The applicant thanks the examiner for pointing out the duplicative phrase. The applicant has amended claim 8, above, to remove this duplication.

The examiner has rejected the claims because the dependent claims narrow the scope of the independent claims, citing to Ex parte Wu. This is an improper rejection since the purpose of dependent claims is to narrow the scope of independent claims.

As far as the inclusion of the term "monounsaturated alcohols" before the recitation of the particular monounsaturated alcohols, this does not lead to indefiniteness or vagueness. In fact, this increases the clarity since it alerts the reader that there is a

single double bond in the formulation of the alcohol. While the terminal "enol" portion of each alcohol name accomplishes the same, since this is found at the end of a long, complex chemical name, it would be easy for even one of extraordinary skill, let alone one of ordinary skill, in the arts to overlook the significance of the "e". Thus, inclusion of the term monounsaturated alcohol" ensures the requisite clarity of understanding wanted in claims language and does not raise a question as to whether the feature "monounsaturated alcohol" is exemplary.

As far as the term "preferably", found in claims 3, 9, 15, 21, 27, ~~29-30, 35-36, 86-87, and 89-90~~ 33 and 87, the applicant is mindful of the examiner's view that this may raise a question as to whether the feature introduced is exemplary or required. Therefore, the applicant has amended the claims above to replace "preferably" with "comprising".

Finally, the examiner feels that the phrase term "suspected" in the phrase "mammal suspected" found in claims 14, 20, 26, 32 and 86 renders these claims (and any claims dependent upon these claims) indefinite. The applicant is mindful of the examiner's view that there is no standard for ascertaining the requisite degree for "suspected". Therefore, the applicant has amended these claims above to replace the term "mammal suspected of having a viral infection" with "mammal to be treated", which does not introduce new matter.

Therefore, the applicant respectfully requests that the examiner withdraw the instant rejection.

Claim Rejections - 35 U.S.C. § 103

The examiner has rejected claims 2-3, 5-6, 8-9, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 as being obvious over Katz '392 in view of Arquette (WO 99200224) and Katz '794 and Katz '107.

The examiner feels that Katz '392 discloses that long chain fatty acids broadly including oleic acid (C18, one double bond) or monounsaturated long chain alcohols broadly (e.g., C18-C28) in their effective amounts with a physiologically compatible carrier are useful in a pharmaceutical composition for topical application and intra

muscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity (citing the abstract, col. 1 lines 10-15, and 20-47; col. 2 lines 12-15; col. 3, lines 18-21; and examples 14-15 at col. 22-23).

The examiner admits that the prior art does not disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts herein in a pharmaceutical composition, which are further comprising the fatty acid esters herein, in a method for treating virus-induced and inflammatory disease of skin and membranes. Also, the prior art does not expressly disclose the effective amounts of active agents in the composition herein to be administered.

The examiner points out that Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (in the abstract and page 3, lines 15-22), jojoba oil (known to contain the instant fatty acids, see page 4 entirely), and the instant fatty acid esters in their various percentages (see pages 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims).

The examiner feels that Katz (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 24 % by weight (see the abstract, col. 3, lines 63-68, and claims 1-2).

Also, the examiner feels that Katz (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 to 2 g/ 50kg of body weight (see the abstract, col. 3, lines 63-38, and claims 1-2).

The examiner feels that it would have been obvious to a person of ordinary skill in the art at the time of the invention to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, that may further comprise the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes and to optimize the effective amounts of active agents in the composition hereon to be administered. The examiner feels that one of ordinary skill would have been motivated to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, which may further comprise the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes since long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts with a physiologically compatible carrier are know to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity based on Katz et al., Moreover, the instant fatty alcohols at least 10% by weight, the instant fatty acids, and the instant fatty acid esters in their various percentages with a physiologically compatible carrier are known to be useful in a pharmaceutical composition for topical applications according to Arquette et al. Therefore, one of ordinary skill in the art would have reasonably expected to combine the instant fatty alcohols, the instant fatty acids, and the instant fatty acid esters, as taught in Arquette et al., in a pharmaceutical composition that would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes since these components are known to be useful in treating virus-induces and inflammatory diseased of skin and membranes.

Further, the examiner feels that since all the active composition components, herein, are known to be useful to treat virus-induced and inflammatory disease of skin and membranes, the examiner feels that it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected.

Additionally, the examiner feels that one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known effective amounts of known active agents to be administered according to the disclosures of Katz et al. and Arquette et al., is considered well within the skill of artisans.

The applicant respectfully disagrees with the examiner. As the examiner noted, Katz '392 discloses long chain alcohols used in antiviral treatment compositions, but does not disclose the specific physiologically compatible carrier claimed in the instant invention. Arquette et al. discloses an emollient composition. Arquette does not teach or suggest that this emollient composition has any medical benefits. At most, Arquette teaches that the emollient of Arquette may be used along with additional medical or pharmaceutical ingredients. In deed, there is no indication in Katz or Arquette as to whether the specified salts of fatty acids or mixed esters would interfere with any medical benefit of the long chain alcohols. None of the Katz references ('392, '794, or '107) teach or disclose the medical effects of the instant salts of fatty acids or mixed esters. It is only in the present invention that the benefits of combining the claimed long chain alcohols with the specified salts of fatty acids or mixed esters has been discovered and disclosed.

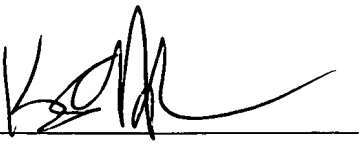
Because none of the prior art references, either individually or in combination, discuss the possible antiviral efficacy of was previously known as an emollient composition, it is not obvious to one of ordinary skill in the arts. In fact, one of ordinary skill in the arts would consider an emollient composition as a barrier composition that would inhibit intercellular antiviral activity. Therefore, the antiviral activity of the instant invention is surprising and unexpected.

For these reasons, the applicant respectfully requests the examiner allow the instant claims, as amended.

In re Application of:	Brown	Art Group:	1614
Serial No.:	09/899,432	Examiner:	Jiang
Atty. Docket No.:	511-051		

Respectfully submitted,

Date: 10/29/03



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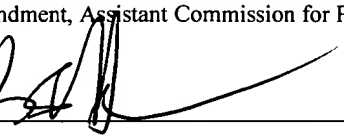
on 10/29/03 By:  .